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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,445	11/13/2001	A. Neil Barclay	DX 01052K1	1467

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EXAMINER	
QIAN, CELINE X	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,445	BARCLAY ET AL.	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *1 and 3-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/17/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *seq.compliance*.

DETAILED ACTION

Claims 1-8 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group III, claim 2, and SEQ ID NO: 20 in the response filed on 3/22/04 is acknowledged. The traversal is on the ground(s) that SEQ ID NO:4 shares close sequence identity with SEQ ID NO:20, thus a binding compound that binds to SEQ ID NO:20 should also bind to a large portion of SEQ ID NO:4. Applicants therefore request that SEQ ID NO:4 be examined together with SEQ ID NO:20.

This argument has been fully considered but is not found persuasive. Although SEQ ID NO:4 share sequence identity with SEQ ID NO:20, whether a binding compound of SEQ ID NO:20 would also bind to SEQ ID NO:4 would depend on which portion of the polypeptide said compound is bind to. For example, if the epitope is from the region of polypeptide of SEQ ID NO: 20 that differs from SEQ ID NO:4, the antibody generated from said epitope would not bind to SEQ ID NO:4. As such, a binding compound of SEQ ID NO:20 is structurally and functionally different from a binding compound of SEQ ID NO:4, hence they do not share a common special technical feature. Thus, the unity of the invention between these binding compounds does not exist.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1 and 3-8 are withdrawn from consideration for being directed to non-elected subject matter. Claim 2 is currently under examination.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The amino acid sequences disclosed in table 5, page 38-39, are not identified by their sequence identifier (i.e., SEQ ID NO:). Applicant is reminded that the entire specification and figures should be reviewed for sequence disclosures and that each sequence disclosed in the specification must be identified by its sequence identifier (i.e., SEQ ID NO:). The specification must be amended to identify all disclosed sequences by their sequence identifier (i.e., SEQ ID NO), in accordance with 37 CFR 1.821(d).

Priority

Acknowledgment is made of applicant's claim for foreign priority based on two applications filed in United Kingdom on 5/13/99 and 11/3/99. It is noted, however, that the copies of a certified copy of the priority documents are missing from the filed. A request has been sent to IB for both documents.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see for example, page 86). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 2 is objected to for containing non-elected subject matter. Applicant elected SEQ ID NO: 20 for examination, whereas Table 1-3 contain a number of different polypeptides. Further, claim 2 is dependent on claim 1, which comprises multiple inventions that are directed to non-elected subject matter. Applicant is advised to re-write the claim in independent form to include the limitation of the parent claim, and only directed to elected invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 2 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claim is drawn to a binding compound comprising an antigen binding site from an antibody, which specifically binds to a natural OX2RH polypeptide selected from: a) a substantially pure or recombinant polypeptide comprising at least three distinct non-overlapping segments of at least four amino acid identical to segments of SEQ ID NO:20; b) a substantially pure or recombinant polypeptide comprising at least two distinct non-overlapping segments of at least five amino acid identical to segments of SEQ ID NO:20; c) a natural primate sequence comprising SEQ ID NO:20; d) a fusion polypeptide comprising primate OX2RH1.2 sequence. The asserted utility of said binding compound is not specific and substantial because the asserted utility of the polypeptide which the binding compound binds to is not specific and substantial. The specification teaches that SEQ ID NO:20 is identified by sequence homology to a rat polypeptide encoded by SEQ ID NO:2 that binds to OX2 antigen. However, the specification

does not teach any function or biological activity for either polypeptide. Although Applicants assert that the polypeptides is a receptor for OX2, the function of said receptor is not taught in the specification or in the prior art. As such, there is no well established utility for such receptor, and the asserted utility of the receptor is neither substantial nor specific to an OX2. Thus, the binding compound to the receptor also lack substantial and specific utility. Furthermore, the claim encompasses a large number of polypeptides that share sequence homology with segments of SEQ ID NO:20, or fusion proteins. They encode proteins that may have different function than that of the protein encoded by SEQ ID NO:20. The specification does not teach any specific and substantial utility of said polypeptides either. Therefore, the binding compounds for these polypeptides of different function also lack specific and substantial utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought,

[the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The claim is drawn to a binding compound comprising an antigen binding site from an antibody, which specifically binds to a natural OX2RH polypeptide selected from: a) a substantially pure or recombinant polypeptide comprising at least three distinct non-overlapping segments of at least four amino acid identical to segments of SEQ ID NO:20; b) a substantially pure or recombinant polypeptide comprising at least two distinct non-overlapping segments of at least five amino acid identical to segments of SEQ ID NO:20; c) a natural primate sequence comprising SEQ ID NO:20; d) a fusion polypeptide comprising primate OX2RH1.2 sequence. The claimed invention encompasses potentially a large genus of binding compounds including antibodies, fragments of antibodies, labeled antibodies/fragments or conjugated antibodies/fragments against a large number of unrelated polypeptides. For instance, a polypeptide comprising at least three distinct non-overlapping segments of at least four amino acid identical to segments of SEQ ID NO:20 may be a protein with entirely distinct structure and function from the polypeptide of SEQ ID NO:20.

Likewise, a polypeptide comprising at least two distinct non-overlapping segments of at least five amino acid identical to segments of SEQ ID NO:20, a polypeptide comprising SEQ ID NO: 20 or a fusion polypeptide comprising primate OXRH1.2 also may be a protein with entirely distinct structure and function from the polypeptide of SEQ ID NO:20. As such, the antibodies or binding compounds to such large number unrelated polypeptides are also unrelated. The specification only describes two antibody, MRC OX88 and OX 102, that bind to the OX2 receptor on rat peritoneal macrophages. The specification fails to disclose other antibodies or binding compounds that are raised against polypeptide with structure and function unrelated to the OX2 receptor. The specification also fails to teach what structural feature such antibodies or binding compounds must share for them to function as a binding compound as claimed. As such, the specification fails to describe a representative number of species by their complete structure or other identifying characteristics. Therefore, the written description requirement is not satisfied.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples;

(f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

The nature of the invention

The claim is drawn to a binding compound comprising an antigen binding site from an antibody, which specifically binds to a natural OX2RH polypeptide selected from: a) a substantially pure or recombinant polypeptide comprising at least three distinct non-overlapping segments of at least four amino acid identical to segments of SEQ ID NO:20; b) a substantially pure or recombinant polypeptide comprising at least two distinct non-overlapping segments of at least five amino acid identical to segments of SEQ ID NO:20; c) a natural primate sequence comprising SEQ ID NO:20; d) a fusion polypeptide comprising primate OX2RH1.2 sequence.

The breadth of the claim

The breadth of the claim is very broad. The claim encompasses any binding compound that comprises an antigen binding site from an antibody which specifically binds to a natural OX2RH polypeptide, wherein said polypeptide is selected from: a) a substantially pure or recombinant polypeptide comprising at least three distinct non-overlapping segments of at least four amino acid identical to segments of SEQ ID NO:20; b) a substantially pure or recombinant polypeptide comprising at least two distinct non-overlapping segments of at least five amino acid identical to segments of SEQ ID NO:20; c) a natural primate sequence comprising SEQ ID NO:20; d) a fusion polypeptide comprising primate OX2RH1.2 sequence. Such polypeptide encompasses potentially a large number of protein of different structure and function which may or may not be an OX2 receptor. Thus, the claim encompasses a large number of binding

compounds including antibodies or fragment of antibodies that bind to proteins of different structure and function.

The guidance from the specification and working examples

The specification does not teach how to use the claimed polypeptide and binding compound. The specification teaches only two polypeptides from rodent species have been confirmed by specific binding to OX2 (see page 18, 2nd paragraph), however, no function or biological activity is given to these polypeptides. The specification fails to disclose whether the polypeptide encoded by SEQ ID NO:20 can bind to OX2. The specification also fails to disclose any function or biological activity of the protein encoded by SEQ ID NO:20. As such, whether the protein encoded by SEQ ID NO:20 is a OX2 receptor is unpredictable. Furthermore, the specification fails to teach whether the large number of claimed polypeptides can either bind to OX2, or possess biological activity of a OX2 receptor. Thus, whether the claimed polypeptides are OX2 receptor is unpredictable, and the function of a OX2 receptor and the claimed polypeptides is also unpredictable. Thus, the specification fails to teach how to use the claimed polypeptide. Since one skilled in the art would not know how to use the claimed polypeptides, the skilled artisan would not know how to use a binding compound that binds to a polypeptide of unknown function. Without teaching from the specification, the skilled artisan would have to turn to prior art for guidance on how to use the claimed binding compounds.

The state of prior art and the level of predictability

The state of art at the time of filing suggests that sequence identity alone is insufficient to accurately predict its biological activity, and that sequence comparison cannot be used solely to determine function. Bork (Genome Research, 10:348-400, 2000) clearly teaches the pitfalls

associated with comparative sequence analysis for predicting protein function because of known error margins for high-throughput computational methods. Bork specifically teaches that computational sequence analysis is far from perfect, despite the fact sequencing itself is highly automated and accurate (page 398, column 1). One of the reasons for this inaccuracy is that the quality of data available is still insufficient. This is particularly true for data relating to protein function. Protein function is context dependent, and both molecular and cellular aspects must be considered (page 398, column 2). Many bioinformatic methods have difficulty exceeding a 70% prediction accuracy. (see page 400, column 1, 2nd paragraph, lines 1-5). In addition, Smith et al (Nature Biotechnology 15:1222-1223, 1997) indicates that there are numerous cases in which proteins of very different function are homologous (page 1222, third column, last paragraph). Furthermore, Brenner (TIG 15:132-133, 1999) teaches the difficulty of accurately infer function from homology, and clearly states that most homologs have different molecular and cellular functions (column 2, second paragraph, page 132). Examples of pitfalls associated with comparative sequence analysis for predicting protein function in enzymes associated with modification of fatty acids are shown by Broun et al. (Science 282:1315-1317, 1998) and Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995). Broun et al. teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydroxylase and as few as six amino acid substitutions can transform a hydroxylase to a desaturase (see abstract). Similarly, Van de Loo et al. teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* where found to be hydroxylase once tested for activity (see abstract).

Based on the teaching from the prior art, whether the polypeptide encoded by SEQ ID NO:20 is a OX2 receptor is unpredictable because the function of a polypeptide cannot be

predicted solely on the sequence homology. Likewise, whether polypeptides share sequence homology with SEQ ID NO:20 are OX2 receptor is also unpredictable. The prior art is silent on the structure and function of a OX2 receptor. The prior art is also silent on the function or biological activity of the various polypeptides recited in the claim. As such, one skilled in the art would not know how to use the claimed polypeptide without undue experimentation. Consequently, one skilled in the art would also have to engage in undue experimentation to use a binding compound that binds to such polypeptide. Therefore, the claimed invention is not enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites a binding compound comprising an antigen binding site from an antibody, which specifically binds to a natural OX2RH polypeptide of claim 1, wherein limitations a) through e) is recited. It is unclear whether limitations of a) through d) is in combination or alternative. In addition, it is also unclear whether limitations of i) through x) under e) is in alternative or combination form. As such, the metes and bounds of the claim cannot be established.

The recitation of "a natural sequence primate OX2RH1.2 polypeptide" also renders the claim indefinite because it is unclear which composition Applicants are referring to, a sequence, primate, or polypeptide?

Claim 2 recites the limitation "a natural OX2RH polypeptide of claim 1" in line 2. There is insufficient antecedent basis for this limitation in the claim. The parent claim 1 does not always recite this limitation. Claim 1 is drawn to a composition of matter selected from: g1)... through g4)... Only g3) recites "a natural sequence," whereas g1, g2 and g4 are drawn to a substantially pure or recombinant polypeptide, or a fusion polypeptide. Therefore, the limitation "a natural OX2RH polypeptide of claim 1" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Preston et al. (1997, Eur. J. Immunol. Vol 27 : 1911-1918, see IDS).

Since it is unclear whether the limitation of a) through e) is in alternative or combination, the claim is given the broadest interpretation. Claim 2 is drawn to a binding compound comprising an antigen binding site from an antibody, which specifically binds to a natural OX2RH polypeptide, wherein the OX2RH is from a rodent.

Preston et al. disclose a monoclonal antibody, MRC OX88, that binds specifically to OX2 ligand on macrophages (see abstract, lines 8-10, and page 1916, 2nd col., 3rd paragraph, lines 4-

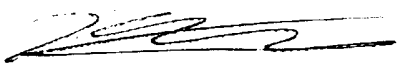
8). According to the teaching of the specification, the antibody used to clone the OX2 receptor, OX102, also binds specifically to rat macrophages. Both MRC OX 88 and OX102 prevent the specific binding of OX2 molecule to rat peritoneal macrophages (see specification, page 17, 2nd and 3rd paragraph). Absent evidence from the contrary, both antibodies bind specifically to the same surface molecule of peritoneal macrophages (although the nature of the OX2 ligand is unknown), and MRC OX 88 is an antibody that binds specifically to a natural rodent OX2 ligand/receptor polypeptide. Therefore, Preston et al. disclose the instantly claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.



Notice to Comply	Application No.	Applicant(s)	
	10/009445	Barclay et al.	
	Examiner	Art Unit	
	Celine Qian	1636	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒7. Other: The amino acid sequences listed in table 5 do not have sequence identifier.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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